

App. No.: 10/647,393  
Amendment Dated February 22, 2007  
Attorney Docket No.: 60589.000013

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### REMARKS

#### I. Election Requirement

It was stated in the Office Action that Applicants' traversal of the election requirement in the reply filed on July 28, 2006 was not found persuasive because each group has different features, requiring different search terms in electronic searches and different classified searches which, allegedly, resulted in burden on the US Patent and Trademark Office ("PTO"). Applicants continue to traverse this restriction requirement and preserve all their rights to pursue the subject matter of non-elected claims.

#### II. Specification and Claim Amendments

Applicants amended portions of the Specification to correct minor typographical and stylistical errors. Applicants amended some claims to improve their form. No new matter is introduced by these amendments.

#### III. 35 U.S.C § 112 Rejection

Claims 1-10, 12-23 and 46 were rejected under 35 U.S.C. § 112, second paragraph, because, allegedly, certain recitations in claims 1 and 12 were unclear. In claim 1, the allegedly unclear recitation was "engaging with opposite edge portions thereof" in the last two lines of that claim, because it was unclear what is "engaging" and to what "thereof" refers.

At the outset, Applicants respectfully submit that claim 1, prior to its amendment herein, was definite because it enabled persons of ordinary skill in the art, familiar with Applicants' specification, to readily ascertain the metes and bounds of the protection sought in claim 1. Nonetheless, Applicants amended claim 1 to expedite prosecution. The amended claim 1 continues to be definite.

Claim 12 was alleged to be unclear as a whole because it was questioned whether claim 12, dependent from claim 1, was trying to claim the holder alone. It was

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asserted that if that were the case, claim 12 was broader than claim 1 and it did not further limit claim 1. (See Office Action, Page 2).

Again, Applicants submit that claim 12 (prior to its amendment herein) readily apprised persons of ordinary skill in the art of the metes and bounds of its scope. It was apparent from claim 12 that it further limited claim 1 because it provided additional details of the holder. In the interest of expediting prosecution, Applicants amended claim 12, which continues to be definite.

Since the remaining rejected claims 2-10, 13-23 and 46 are dependent from claims 1 or 12, they are also definite.

#### **IV. 35 U.S.C. § 102 Rejections**

##### **A. Rejection over Maynard et al..**

Claims 1-4, 6, 8-10, 12-15, 17-23 and 46 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,287,783 to Maynard et al. ("Maynard"). Applicants respectfully traverse this rejection.

Claims 1 and 12 are the only independent claims in this rejection. Thus, if claims 1 and 12 are patentable, then all the claims dependent from claims 1 and 12 are also patentable.

It was asserted that "Maynard teaches a reagent containing... planar test member 16, 18, abutting surface 32 of holder 12 and retained on opposite edge portions by tabs 58, shaped as claimed." Office Action, page 3. It was also stated that the devices have upper and lower surfaces and their structure is capable of being stacked. Column 7, line 46, of Maynard was particularly relied upon. *Id.*

Applicants respectfully traverse this rejection. At the outset, it is submitted that to anticipate claims 1 and 12, Maynard must disclose every limitation of these claims, arranged in the same order as set forth in the claims. Maynard fails to satisfy that standard.

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Maynard is directed to an optical assay device comprising a base 12 and a generally round member 14. The base 12 carries an absorbent material 16, and the member 14 a test membrane or an optical stack 18. (See column 5, lines 15-18). The absorbent material 16 is retained in the base 12 by the retaining tabs 58. (See column 6, lines 11-13, column 9, lines 32-37 and Figs. 1, 5.) The mechanism used to retain the absorbent material by the tabs does not appear to be described by Maynard. In contrast, Applicants' claim 1 recites, *inter alia*:

a holder including retaining means...comprising projections, which are...tooth-shaped with pointed ends... at least some of the projections comprising a leading edge forming a ramp sloping towards a plane defined by the abutment surface ...said leading edge forms a cutting edge for at least partly cutting into the edge portion of the test member so as to facilitate insertion of the test member into the holder when the test member is moved into engagement with said abutment surface...

The projections of Maynard (e.g., retaining tabs 58, Fig. 1) do not have a leading edge forming a ramp sloping towards a plane defined by the abutment surface and forming a cutting edge for at least partly cutting into the edge portion of the test member. For at least this reason, Maynard fails to anticipate Applicant's claim 1.

Applicants' claim 12 also recites:

a holder including a receiving and retaining means comprising ...projections, which are ...tooth-shaped with pointed ends ...providing at least some of the projections with a leading edge forming a ramp sloping towards a plane defined by said abutment surface and wherein said leading edge forms a cutting edge for at least partly cutting into the edge portion of the test member when the test member is moved into engagement with said abutment surface while the projections engage with opposite edge portions of the test member.

For the reasons similar to those set forth above regarding claim 1, Maynard fails to anticipate Applicants' claim 12 at least because he does not disclose a holder having the receiving and retaining means defined in claim 12.

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### **B. Rejection Over Sun**

Claims 1-10, 12-23 and 46 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,372,516 to Sun. It was asserted that Sun teaches a test member 14, 16, 18, having reagents in it, in a holder 20 having an abutment surface on the bottom surface 26, 28 of the top half 22. Column 2, lines 60-67 and Figures 11, 13 were particularly relied upon in this assertion. It was also stated that Sun provides various projections down the center of a base 24, which are differently spaced from the abutment surface (Fig. 12), in the assembled device. It was also asserted that the edges of the projections engaged the edges of the test member and that some of the projections are pointed with sloping surfaces, while others have planar surfaces parallel to the abutment surface. (See Office Action, page 4).

Applicants respectfully traverse this rejection.

As with the rejection over Maynard, claims 1 and 12 are the only independent claims in this grouping of claims. Accordingly, if claims 1 and 12 are patentable over Sun, all the remaining claims rejected over Sun are also patentable.

Sun is directed to a lateral flow test device which includes a top half 22, and a bottom half 24 (col. 2, lines 34-36; Figs. 1, 3). Sun discloses a number of bumpers. For example, the device comprises a membrane 16, held in place by elongated bumpers 38a-38c in the interior of the top half 22. Elongated bumpers 40a - 40e in the top half 22 aid in holding a test strip 18 in place. (col. 2, lines 52-56, Fig. 11). The bottom half 24 has a projection 42 and a stop member 44. None of these bumpers or projections have or are projections which are tooth-shaped, with pointed ends, and with some of the projections including a leading edge forming a sloping ramp, the leading edge forming a cutting edge to at least partially cut into the edge portion of a test member, as required by Applicants' claims 1 and 12.

All the remaining claims depend either from claim 1 or claim 12 and are consequently novel over Sun.

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**V. Conclusion**

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance, and an early indication of the same is courteously solicited. The Examiner is respectfully requested to contact the undersigned by telephone at the below-listed telephone number, in order to expedite resolution of any issues and to expedite passage of the present application to issue, if any comments, questions, or suggestions arise in connection with the application.

No fee, other than stated herein, is believed due for entry and consideration of this timely Reply. Nevertheless, in the event that the U.S. Patent and Trademark Office requires any additional fee to enter this Reply or to maintain the present application pending, please charge such fee to the undersigned's Deposit Account No. 50-2478.

Respectfully submitted,

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Dated: February 22, 2007

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